K040684

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## Spectros Corporation

NOV - 5 2004 4370 Alpine Road #108, Portola Valley CA 94028-7927
Phone 650.851.4040 Fax 650.851.4099

David A. Benaron, M.D.
e-mail: dbenaron@spectros.com

## Section 40 – 510(k) Summary

[This section supersedes and replaces **Section 29** of the Application]

### I. Applicant Information

A. Date of Summary: October 28, 2004

B. Manufacturer
Spectros Corporation
4370 Alpine Road, Suite 108
Portola Valley CA 94028

C. Official Contact:
David A. Benaron, MD
CEO and President
Spectros Corporation
Suite 108
4370 Alpine Road
Portola Valley CA 94028

D. Contact Info:
Phone: (650) 851-4040
Fax: (650) 851-4099
E-mail: dbenaron@spectros.com

### II. Device Information

A. Proprietary Name: T-Stat™ 303 Microvascular Tissue Oximeter

B. Common Name: Tissue Oximeter

C. Classification Name: Oximeter, Tissue (870.2700)

D. Product Code: MUD

E. Regulatory Class: Class II

F. Panel: Cardiovascular

## III. Predicate Devices

The following devices are cited as predicates:

**Exhibit 40-1**
**Predicate Tissue Oximeter Devices Summaries**

| # | Predicate Feature | Manufacturer | Device | K-Number |
|---|---|---|---|---|
| 1. | Tissue Oximeter | Hutchinson | InSpectra 325 | K023938 |
| 2. | Tissue Oximeter | Somanetics | Invos 5100 | K001842 |
| 3. | Relative Hemoglobin | Nellcor | N-395 | K991823 |
| 4. | Site-Specific: Oral | Olympus | XENF-DP | K011869 |
| 5. | Site-Specific: Colon | Olympus | LF-DP | K002231 |
| 6. | Site-Specific: Endo | Olympus | Thoracoscope / Laparoscope | K915857 |

## IV. General Description

The Spectros T-Stat™ 303 Tissue Oximeter is a broadband, multiwavelength, Visible Light Spectroscopy (VLS) monitoring system for measuring the saturation of hemoglobin with oxygen in the microvascular tissue spaces ($StO_2$%).

The complete system consists of a disposable sensor probe connected to a software-driven electronic monitor. Data collection, analysis, and display functions are provided by the monitor. Illumination of the tissue is provided by a visible light source in the sensor probe placed near, on, or into the target tissue to be studied. Reflected light is captured and returned to the monitor via a detachable connection at the monitor end of the patient probe. $StO_2$% is estimated using differential optical diffuse reflectance spectroscopy and fitting for background scattering over a range of reflected visible wavelengths.

## V. Indications

The Spectros T-Stat™ 303 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces ($StO_2$%) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states.

The prospective clinical value of measurements made with the T-Stat™ Oximeter has not been demonstrated in disease states. The T-Stat™ Oximeter should not be used as the sole basis for diagnosis or therapy.

## VI. *In Vitro* and *In Vivo* Test Data

In studies of T-Stat™:

- T-Stat™ accurately measured hemoglobin spectra and desaturation binding curves in peer-reviewed in vitro studies.
- T-Stat™ $StO_2$% determined using VLS was unbiased in comparison to $StO_2$% determined using NIRS predicates (StO2% Bias = –1% ± 5%, p=N.S.), but VLS demonstrated significantly tighter ranges of normal in peer-reviewed animal and human studies (VLS normal range 62-75% vs. NIRS reported at 48-88%, $p<0.001$).
- T-Stat™ VLS tissue oximetry was demonstrated sensitive to reduced-flow and no-flow ischemic states in peer-reviewed animal and human studies ($p<0.001$).
- T-Stat™ VLS tissue oximetry provides readings in low and no flow ischemic states in human clinical studies.

## VI. Comparison to Predicate Devices

A. Similarities

Both T-Stat™ and the predicate tissue oximeters:

- Use the same fundamental optical operating principle, called diffuse reflectance spectroscopy.
- Use light from an LED to probe a cross-section of the microvasculature of tissue (arterioles, capillaries, and venuole).
- Analyze light returning from tissue, after having passed through the tissue, for hemoglobin in its oxygenated and deoxygenated forms in the optically sampled region.
- Calculate $StO_2$%, a value reflecting the percentage saturation of hemoglobin with oxygen in the microvascular capillary spaces

Both T-Stat™ and the predicate pulse oximeters:

- Use the same fundamental optical operating principle, called diffuse reflectance spectroscopy.

- Analyze light returning from tissue, after having passed through the tissue, for hemoglobin in its oxygenated and deoxygenated forms in the optically sampled region.

- Calculate and display a relative hemoglobin value used for assessment of device functionality, proper probe placement, and system operation.

Both the T-Stat™ and the endoscope predicates:

- Emit visible light into the tissues and detect a portion of the light backscattered from tissues in the oral cavity, colon, endoscopic procedures.

- Use low power light that does not adversely influence the physiology of the target tissue.

B. Differences

T-Stat™ and the predicate Tissue Oximeters differ in the following non-significant ways:

- 2048 *vs.* 4 Wavelengths: T-Stat™ measures light at 2,048 wavelengths; the predicate devices use 4 or fewer wavelengths. An increase in the number of wavelengths used increases the robustness of the matrix solutions by which $StO_2$% is calculated. This is because the solution becomes statistically overdetermined at such large wavelength counts (number of measurements is very much greater than the number of unknowns in the equation).

- VLS *vs* NIRS: T-Stat™ uses only visible light (VLS); the predicates use *both* visible *and* near-infrared light (NIRS). Both methods involve diffuse reflectance spectroscopy; only the wavelength range has changed. Laboratory and clinical values are not changed by the adoption of VLS in favor of NIRS; In vivo, mean VLS $StO_2$% was unbiased compared to NIRS.

- Laser *vs*, Non-Laser LED: T-Stat™ uses a non-laser LED; the predicates use laser LED's. LED choice does not affect the underlying technology of the measurement. The energies emitted by the T-Stat™ non-laser LED and the predicate laser LED's are comparable.

T-Stat™ and the predicate pulse oximeter differ in the following non-significant ways:

- Tissue Oximetry: Pulse oximeters estimate arterial saturation, rather than tissue hemoglobin saturation; however, the predicate for tissue oximetry is

other tissue oximeters, not pulse oximetry, and therefore this difference is not significant.

T-Stat™ and the predicate endoscopes differ in the following non-significant ways:

- Analysis: Endoscopes typically do not provide spectral analysis; however, the predicate for spectroscopic analysis for hemoglobin saturation is tissue and pulse oximetry, not endoscopy, and therefore this difference is not significant.

C. Result of Comparison

The Spectros T-Stat™ 303 Microvascular Tissue Oximeter is substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2004

Spectros Corporation
c/o David A. Benaron, M.D.
CEO & President
4370 Alpine Road, Suite 108
Portola Valley, CA 94028

Re: K040684
Trade Name: Spectros T-Stat™ 303 Microvascular Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: MUD
Dated: July 30, 2004
Received: August 9, 2004

Dear Dr. Benaron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K 040684

Device Name: Spectros T-Stat™ 303 Microvascular Tissue Oximeter

Indications For Use: The Spectros T-Stat™ 303 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces ($StO_2$%) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states.

The prospective clinical value of measurements made with the T-Stat™ Oximeter has not been demonstrated in disease states. The T-Stat™ Oximeter should not be used as the sole basis for diagnosis or therapy.

Prescription Use XXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K040684